DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 6 2004

The Binding Site, Ltd.
c/o Mr. Jay H. Geller
West Tower, Suite 4000
2425 West Olympic Coulevard
Santa Monica, CA 90404

Re: k031016
Trade/Device Name: FREELITE® Human Kappa Free Kit and FREELITE® Human Lambda Free Kit for use on the Dade Behring Nephelometer II
Regulation Number: 21 CFR 866.550
Regulation Name: Immunoglobulin (light chain specific) immunological test system
Regulatory Class: Class II
Product Code: DFH [Kappa]; DEH [Lambda]
Dated: June 10, 2003
Received: June 13, 2003

Dear Mr. Geller:

This letter corrects our substantially equivalent letter of July 15, 2003, regarding the omission of the FREELITE® Human Lambda Free Kit from the trade name information above, and of the product code for the FREELITE® Human Kappa Free Kit, i.e., DFH.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-3084. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman, M.D.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031016

Device Name: FREELITE® Human Kappa Free Kit for Use on the Dade Behring Nephelometer II

Indications for Use: This kit is intended for the quantitation of kappa free light chains in serum and urine on the Dade Behring Nephelometer II (BNII). Measurement of the various amounts of the different types of light chains aids in the diagnosis and monitoring of multiple myeloma, lymphocytic neoplasms, Waldenstrom's macroglobulinemia, amyloidosis, light chain deposition disease and connective tissue diseases such as systemic lupus erythemoatosus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

A P Reeves for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): K031016

Device Name: FREELITE® Human Lambda Free Kit for Use on the Dade Behring Nephelometer II

Indications for Use: This kit is intended for the quantitation of lambda free light chains in serum and urine on the Dade Behring Nephelometer II (BNII). Measurement of the various amounts of the different types of light chains aids in the diagnosis and monitoring of multiple myeloma, lymphocytic neoplasms, Waldenstrom's macroglobulinemia, amyloidosis, light chain deposition disease and connective tissue diseases such as systemic lupus erythemoatosus.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J Reeve for J. Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K031016

Prescription Use ✓ OR Over-The-Counter Use ___
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(Optional Format 1-2-96)